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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,756	10/16/2000	Fatih M. Uckun	12152.76USD1	1604
	7590 06/16/2003			
MERCHANT & GOULD PC P.O. BOX 2903			EXAMINER	
· ·	IS, MN 55402-0903		LIU, HONG	
			ART UNIT	PAPER NUMBER
			1624	10
			DATE MAILED: 06/16/2003	(19

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		09/688,756	UCKUN ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Hong Liu	1624				
Period for	- The MAILING DATE of this communicati n r Reply	appears on the cover sheet	with the correspondence address	-			
A SHO THE M - Extens after S - If the j - If NO - Failure - Any re	DRTENED STATUTORY PERIOD FOR REMAILING DATE OF THIS COMMUNICATION is sions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. Deriod for reply specified above is less than thirty (30) days, a period for reply is specified above, the maximum statutory per to the total period for reply will, by state to reply within the set or extended period for reply will, by state ply received by the Office later than three months after the maximum statement. See 37 CFR 1.704(b).	N. R. 1.136(a). In no event, however, may reply within the statutory minimum of the did will apply and will expire SIX (6) Matute, cause the application to become	a reply be timely filed nirty (30) days will be considered timely. DNTHS from the mailing date of this communi ABANDONED (35 U.S.C. § 133).	cation.			
1)	Responsive to communication(s) filed on 2	27 May 2003 .					
2a)⊠		This action is non-final.					
3)	Since this application is in condition for allo closed in accordance with the practice und on of Claims			rits is			
•	Claim(s) <u>31,34 and 46-50</u> is/are pending in	the application					
	a) Of the above claim(s) is/are withd						
	Claim(s) is/are allowed.	nawn nom consideration.					
· <u> </u>	6)⊠ Claim(s) <u>31,34 and 46-50</u> is/are rejected.						
	☐ Claim(s) is/are objected to.						
	Claim(s) are subject to restriction and	d/or election requirement.					
Application		,					
9) <u></u> ⊤	he specification is objected to by the Exami	iner.	•				
10)∐ T	he drawing(s) filed on is/are: a)□ ac	cepted or b) objected to by	the Examiner.				
	Applicant may not request that any objection to						
11)□ T	he proposed drawing correction filed on	is: a)□ approved b)□	disapproved by the Examiner.				
_	If approved, corrected drawings are required in reply to this Office action.						
	he oath or declaration is objected to by the	Examiner.					
Priority ur	nder 35 U.S.C. §§ 119 and 120						
13) 🗌 🛚	Acknowledgment is made of a claim for fore	eign priority under 35 U.S.C	§ 119(a)-(d) or (f).				
a)[] All b)☐ Some * c)☐ None of:						
1	I. Certified copies of the priority docume	ents have been received.					
2	2. Certified copies of the priority docume	ents have been received in	Application No				
	B. Copies of the certified copies of the page application from the International see the attached detailed Office action for a liest	Bureau (PCT Rule 17.2(a))		!			
	knowledgment is made of a claim for dome	•		cation).			
a)	The translation of the foreign language posteriors are translation of the foreign language posteriors.	provisional application has	peen received.	,			
Attachment(· Ju · · · · · · · · · · · · · · · · · ·				
2) D Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s	5) 🔲 Notice o	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152)				

U.S. Patent and Trademark Office PTO-326 (Rev. 04-01) Art Unit: 1624

DETAILED ACTION

Claims 31, 34, and 46-50 are pending in this application.

Rejection Maintained

Applicants' arguments were fully considered but were not found persuasive. Therefore, rejections to claims 47-50 under 35 U.S.C. 103(a) are maintained for reasons already made of record notwithstanding applicants' traverse.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 46, 31, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Uckun et al. (U S Patent 6,080,747). Uckun teaches the methods of using the compounds (see Table 1, col. 20).

Claim Rejections - 35 USC § 103

Claims 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (WO 95/15758) is maintained for the reasons set forth in the office action mailed in paper No. 7 and 9. Applicants first argue that the mode of action of the reference compounds is to inhibit CSF-1R receptor tyrosine whereas the mode of action of the instantly claimed compounds is inhibition of JAK-3, a non-receptor tyrosine kinase. The distinction drawn by the applicants. although persuasive, is not particularly relevant in the nonobviousness analysis because the claims are not directed to subject matter of inhibition of JAK-3 or CSR-1R. Rather, the claims are drawn to a method of treating inflammation using the 6, 7-alkoxy quinazoline compounds. Therefore, the issue is whether the inflammation caused by CSF-1R abnormality is so different from the JAK-3-mediated inflammation that the reference compounds are only good at inhibiting autoimmune inflammation and the instantly claimed compounds are only effective in treating UVB-radiation induced inflammation. From what applicants' description of these two types inflammation, it appears that both UVB radiation caused inflammation and autoimmune inflammation involve activated macrophage and elevated levels of cytokines. If the quinazoline derivatives are effective in modulating the activated macrophage such that the production of the pro-inflammatory cytokines could be reduced, one would expect that the quinazoline compounds

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could be used to treat autoimmune inflammation and inflammation involving JAK-3 because of the similarity of the underlying mechanisms of these two types of inflammation. Absent experimental evidence showing that the reference compounds are indeed effective in treating autoimmune inflammation but not JAK-3-associated inflammation, applicants' conclusion that "compounds that might inhibit inflammation in the one may not inhibit inflammation in the other" does not seem to stand on a firm ground.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a UVB-induced inflammatory response using the quinazoline derivatives, does not reasonably provide enablement for use of any JAK-3 inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The nature of the invention in the instant application has claims which embrace a diversity of chemically and physically distinct compounds that can be JAK-3 inhibitors. While it is shown in Figure 17 that compound 6 can reduce an UVB-induced inflammatory response, there is no teaching in the specification that any JAK-3 inhibitors, which may not be limited to

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chemical compounds but antibodies or cytokines, could be as effective as compound 6 in reducing the inflammatory response.

This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested. In cases directed to chemical compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. See In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. No reasonable assurance has been made that the instant compounds as an entire class have the required activities needed to practice the invention. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability" have been demonstrated to be sufficiently lacking in the instant case for the scope being claimed.

Because applicants' amendments have not overcome the art rejection, this application is not deemed to be in condition of allowance.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual

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number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

Hong Liu June 12, 2003

Supervisory Patent Examiner

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